ATTACHMENT 1

K080439

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 16 2008

510(k) SUMMARY

PURITAN BENNETT
Sandman Info and Sandman Auto

Submitter Information

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France

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Submission Correspondent	Tina Dreiling Regulatory Affairs Associate II Covidien, formerly Nellcor Puritan Bennett Inc 6135 Gunbarrel Ave Boulder, CO 80301
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Device Name

Proprietary Name	Puritan Bennett Sandman Info and Auto
Common Name	CPAP device
Classification Name	Non continuous Ventilator (73 BZD), per 21 CFR 868.5905

Device Information

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are designed to deliver Continuous Positive Airway Pressure to patients suffering from obstructive sleep apnea. It may be configured with optional humidification.

Predicate Device Equivalence

The Puritan Bennett Sandman Info is equivalent to the Puritan Bennett GoodKnight 420S CPAP device (K020886), with the optional additive functionality of the Puritan Bennett GoodKnight H2O heated humidifier (K042184).

The Puritan Bennett Sandman Auto is equivalent to the Puritan Bennett GoodKnight 420E CPAP device (K020886), with the optional additive functionality of the Puritan Bennett GoodKnight H2O heated humidifier (K042184).

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto, like the predicate devices, are intended to provide Continuous Positive Airway Pressure (CPAP) between 3 and 20 cmH_2O to spontaneously breathing patients over 30 Kg for the treatment of Obstructive Sleep Apnea in a hospital and homecare environment, with optional humidification of the delivered air.

Testing was performed to demonstrate that the performance of the Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto is equivalent to the legally marketed predicate device. The safety and effectiveness of the Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto were verified through performance related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are found compliant and had been certified to the standards referenced in the "FDA Reviewer Guidance for Premarket Notifications".

NOTE: The term "Substantial Equivalence" as used in this 510(k) Premarket Notification submission is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, 21 CFR § 807, Subpart E. A determination of substantial equivalency under this submission is not intended to haveany bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence in this submission shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are designed to deliver Continuous Positive Airway Pressure between 3 and 20 cmH_2O, and may come in different configurations including an optional integrated pass-over or heated humidifier.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto can be powered either by AC mains (100 VAC to 240 VAC nominal) or by an external 12 VDC battery. The blower motor nominal voltage is 13 VDC. The Puritan Bennett Sandman Info and the Puritan Bennett Sandman Auto are double-insulated so that grounding is not required.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are for use by prescription only and displays the appropriate labeling.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are configured for patient use by a homecare dealer according to the prescription using the Clinician Manual provided. The devices are operated according to the instructions contained in the Patient Manual.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto do not contain any drugs or biological products as components. However, the devices can be used to provide the patient with supplemental oxygen.
The device and accessories are not supplied sterile, nor are they intended to be sterilized.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are for multiple use.
The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto contain no patient contact components.
The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto tubing is equivalent to that of the CPAP predicate device.
The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto and the air filter are for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto rely on 1 microprocessor for setting and viewing various control parameters and turning features on and off, and for controlling the heated humidification.

The Puritan Bennett Sandman Info operates only in Constant mode: the main function of the device is to deliver constant positive airway pressure to the patient at a fixed level prescribed by the practitioner.

The Puritan Bennett Sandman Auto operates in either Constant or Automatic mode. In Constant mode, the main function of each device is to deliver constant positive airway pressure to the patient at a fixed level prescribed by the practitioner and between 4 and 20 cmH_2O.

In Automatic mode (APAP mode), the practitioner determines and sets a maximum and minimum pressure range above and below the prescribed reference pressure and between 4 and 20 cmH_2O. The pressure is adjusted within the maximum and minimum limits according to the patient's respiratory pattern and the type of events detected.

Pressure delivery for the Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto is regulated by a pressure sensor which monitors both ambient and output pressure and provides feedback to the control system.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto use software to set the various device parameters such as the prescription pressure and the ramp starting pressure, and to provide heated humidification.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto comply with certain voluntary standards, specifically the draft ARDB Reviewer Guidance for Premarket Notification Submissions (Nov 1993) and IEC60601-1.

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are not part of a kit.

Indication for Use

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are indicated for the treatment of obstructive sleep apnea in spontaneously breathing patients weighing more than 30kg (66lb) within homecare and hospital environments.

Conditions of use

The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are designed for use at home or in sleep centers. This device is portable and can be powered from both household and automobile power sources.
The Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto may come with an integrated heated humidifier, which is designed to heat and raise the humidity of the air delivered to the patient. When the device is battery-powered, the heated humidification feature cannot be used, but pass-over humidification is still possible. The water chamber is designed to be filled with water only.
If Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto do not come with an integrated heated humidifier, pass-over humidification may be achieved by using a water chamber.

Contraindications

There are no contraindications.

Summary of Performance Testing

1. Functional testing confirms that the Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto are capable of meeting its stated performance specifications. The device passed all tests.
2. Testing confirms that the Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto comply with the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The device passed all tests.
3. All software is tested in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 2005. The devices passed all tests.

Conclusions

We conclude that the Puritan Bennett Sandman Info and Puritan Bennett Sandman Auto meet the stated performance specifications and criteria referenced above and that the device and its accessories will operate safely in its intended environment and will be effective in fulfilling the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2008

Mallinckrodt Développement France
C/O Ms. Tina Dreiling
Regulatory Affairs Associate II
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K080439
Trade/Device Name: Puritan Bennett, Sandman Info & Sandman Auto
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 7, 2008
Received: May 8, 2008

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

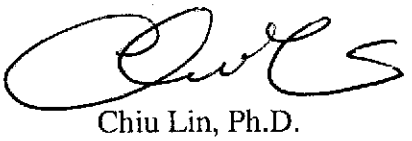
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
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Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Puritan Bennett, Sandman Info & Sandman Auto

Indications for Use:
The Sandman Info and Sandman Auto are indicated for the treatment of obstructive sleep apnea in spontaneously breathing patients weighing more than 30kg (66lb) within homecare and hospital environments.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080439